



Virginia
Regulatory
Town Hall

Final Regulation Agency Background Document

Agency Name:	Board of Pharmacy, Department of Health Professions
VAC Chapter Number:	18 VAC 110-20-10 et seq.
Regulation Title:	Regulations Governing the Practice of Pharmacy
Action Title:	Registration of Pharmacy Technicians
Date:	12/3/02

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

Amendments to regulation are necessary in order to comply with Chapter 317 of the 2001 Acts of the Assembly requiring the Board to promulgate regulations for the registration of pharmacy technicians. The statute requires regulations to specify criteria for the training program, examination, and evidence of continued competency; it further specifies that current certification from the Pharmacy Technician Certification Board qualifies a person for registration.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

No changes to proposed regulations have been made in the adoption of final amendments.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On December 3, 2002, the Board of Pharmacy adopted final amendments to 18 VAC 110-20-10 et seq., Regulations Governing the Practice of Pharmacy, in order to implement a registration program for pharmacy technicians.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

- 1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*
- 2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
- 3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
- 4. To establish schedules for renewals of registration, certification and licensure.*
- 5. To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*

6. *To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 and Chapter 25 of this title.*
7. *To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*
8. *To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.*
9. *To take appropriate disciplinary action for violations of applicable law and regulations.*
10. *To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.*
11. *To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.*
12. *To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.*

The specific statutory mandate for registration of pharmacy technicians is found in § 54.1-3321:

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

- 1. The entry of prescription information and drug history into a data system or other record keeping system;*
- 2. The preparation of prescription labels or patient information;*
- 3. The removal of the drug to be dispensed from inventory;*
- 4. The counting, measuring, or compounding of the drug to be dispensed;*
- 5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;*
- 6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;*
- 7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and*
- 8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.*

B. To be registered as a pharmacy technician, a person shall submit satisfactory evidence that he is of good moral character and has satisfactorily completed a training program and examination that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board.

C. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.

E. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

(2001, c. 317.)

§ 54.1-3322. Denial, revocation, and suspension of registration as a pharmacy technician.

The Board may revoke, suspend or refuse to issue or renew any registration of a pharmacy technician upon determining that the applicant or the registered pharmacy technician:

- 1. Has been negligent as a pharmacy technician;*
- 2. Has engaged in or attempted to engage in any fraud or deceit as a pharmacy technician;*
- 3. Has engaged in acts that may only be performed by a pharmacist;*
- 4. Has become incompetent to perform the duties of a pharmacy technician because of a mental or physical condition;*
- 5. Uses drugs or alcohol to the extent that he is rendered unsafe to perform the duties of a pharmacy technician;*
- 6. Has violated or cooperated with others in violating any provision of law relating to the practice of pharmacy or of any regulation of the Board;*
- 7. Has been convicted of any felony or any crime involving moral turpitude, or has been convicted of violating any federal drug law or any drug law of Virginia or any other state or jurisdiction; or*
- 8. Has been prohibited from performing the duties of a pharmacy technician by any other state, or has been prohibited by a health regulatory board of any state or by any federal agency from practicing, or assisting in the practice of, any health care profession.*

(2001, c. 317.)

The Assistant Attorney General who provides counsel to the Board has certified that the Board has the authority to promulgate the amended regulations and that they do not conflict with existing state or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

Chapter 317 of the Acts of the Assembly (HB 1826; Delegate Morgan) mandated that the Board of Pharmacy adopt final regulations for the registration of pharmacy technicians by July 1, 2003. As required by § 54.1-3321 of the Code of Virginia, regulations must establish the criteria for training and examination necessary for registration and requirements for evidence of continued competency as a condition of renewal. Consistent with the mandate in § 54.1-2400, the Board must also establish fees to support the regulatory and disciplinary activities related to registration of pharmacy technicians and any other qualifications necessary to ensure competence and integrity.

While certain aspects of regulating the new occupation are already set in the Code, amendments to 18 VAC 110-20 are necessary to establish the educational and testing criteria for registration of technicians that are essential to ensure that technicians are competent to work with the preparation of prescription drugs. While the pharmacist remains responsible for the work of technicians under his supervision, the Board had an obligation to develop criteria for technician registration that are sufficient to provide for the health, safety and welfare of the public dependent on the accuracy and integrity of prescription drugs. Therefore, an applicant for registration is required to be trained in the knowledge and skills necessary to perform the technician tasks permitted by law and to pass an examination establishing minimal competence in that core knowledge.

Though the Code permits persons enrolled in a pharmacy technician training program to engage in the acts restricted to a registered technician for the purpose of gaining practical experience, the regulations set a limitation on the length of time a person may work within a training program. The Code also requires that regulations address continued competency for renewal of registration, so amendments were necessary to specify the number of hours of continuing education and the approved providers. Amendments to fees charged by the Board were promulgated to provide an application fee, renewal fee and other miscellaneous fees as necessary to cover the anticipated administrative and disciplinary functions related to registration and practice of pharmacy technicians.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

The substantive provisions in the amended regulations primarily involve setting criteria for training, examination and utilization of pharmacy technicians registered by the Board. An applicant for registration must either provide evidence of current certification by the Pharmacy Technician Certification Board (PTCB) or complete a board-approved training program and pass a board-approved examination. To establish an approved training program, an entity must apply to the board and provide evidence that the curriculum will instruct in the applicable laws and regulations and in the tasks restricted to pharmacy technicians. Instructors are required to be licensed pharmacists, pharmacy technicians with one year of experience who are registered in Virginia or certified by PTCB, or other persons approved by the board. Pharmacies may permit a person to perform tasks that are restricted to registered technicians while that person is in a training program for no more than nine months without having that person registered. A pharmacist may monitor no more than two trainees at any one time and supervise no more than four persons, including both technicians and trainees.

Every pharmacy that employs technicians is required to maintain a site-specific training program and manual to teach such functions as proper use of equipment and computers and performing pharmacy calculations consistent with the pharmacy's practice. The examination must test entry-level competence, meet recognized test measurement standards, and be administered by an independent third party.

For renewal of registration, the technician must attest to having five contact hours of continuing education in an approved CE program. Provisions are made for extensions and exemptions of requirements and for maintenance of documentation. Fees are set at \$25 for an application or annual renewal and \$150 for approval of a training program.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

During 2000, members of the Board worked in conjunction with representatives of various pharmacy groups on the possible regulation of pharmacy technicians. Most of the issues related to registration v. licensure, the ratio of pharmacist to technicians, the duties and responsibilities of technicians, and the criteria for registration were debated and resolved prior to the introduction of legislation in 2001. Therefore, the major issues addressed through regulation were the training and examination necessary for registration.

1) The primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions:

There are numerous factors which have increased workload and stress in pharmacies today including a significant increase in prescription volume, shortages in the pharmacist work pool, shrinking reimbursement for dispensed prescriptions, increased workload in processing prescriptions due to increased steps in processing insurance claims and increased numbers of

patients participating in prescription payment plans, increased numbers of drugs in inventory, and greatly increased numbers of drugs in pharmacy inventories. These pressures have exposed many pharmacists to excessive workloads with greater risks for making dispensing errors. In a small percentage of pharmacies, new technology and robotics have been useful in addressing the problem, but in the vast majority of situations, especially retail pharmacies, the pharmacy is using the pharmacy technician to assist the pharmacist with the workload. In response to this need to handle the increasing workload, the Board several years ago increased the ratio of pharmacist to technicians from 1:1 to 1:3, provided the technician held a national credential as assurance of minimal competence. It is estimated that as many as a third to a half of the technicians now hold that credential (PTCB). While this did prove helpful in some settings, there are not enough PTCB certified technicians to meet the demand. The PTCB examination is only administered three times a year, and is a relatively difficult examination.

While there was a recognition of the need to allow pharmacists to supervise more technicians to handle workload, there was also a serious concern about the lack of training for some technicians and the absence of criteria for minimal competence as well as lack of accountability for the technician. Pharmacists were then and remain responsible for checking the final prescription product before it is dispensed, but a number of dispensing errors have been made by technicians and not caught by the checking pharmacist prior to dispensing.

For this reason, the General Assembly amended the Code to require registration of technicians and mandated the Board to establish educational, training and examination qualifications. The amended rules have set minimal criteria for training in an approved program and for passage of an examination in order to make registration accessible to most persons currently working in the pharmacy. There are several advantages to the public. By requiring registration, the Board will have the ability to hold the technician accountable for his actions and will be able to take action against the registration if warranted which will keep a technician who is impaired, incompetent, or otherwise not authorized to perform technician tasks from leaving one pharmacy and becoming employed by another. There will be consistent standards for training and testing providing greater assurance to the public that the persons working in the prescription department are knowledgeable in their tasks. Because of the pharmacist shortage and low reimbursements, hiring additional pharmacists is usually not an option for pharmacies with excessive workload. Pharmacies will benefit from being able to have one pharmacist supervise up to four technicians, thus increasing the capacity to provide quality pharmacy services without hiring additional pharmacists.

As with any restrictions in the ability to perform certain tasks, those restrictions may create temporary shortages in the workforce. A disadvantage to pharmacies may be higher wages demanded by registered technicians although most pharmacies already offer incentive programs with higher wages to a technician who obtains PTCB certification, because performance and retention improves. Pharmacies may have employees who are currently performing technician tasks who are not able to qualify for registration or who choose not to meet criteria for registration. These employees will not be able to continue to perform technician duties, but may be retained to perform clerical tasks. Pharmacies may have some expenses associated with costs of training personnel to meet criteria for registration, or in recruiting persons who already meet requirements.

2) The primary advantages and disadvantages to the agency or the Commonwealth:

There are no discernable advantages or disadvantages to the agency or the Commonwealth. The fee structure set in regulation is intended to ensure that costs related to review and approval of training programs and of applicants for registration is covered by application fees. The renewal fee of \$25 is intended to offset an increase in the disciplinary workload of the agency, related to complaints, investigations, and cases docketed against technicians. Without any history for such complaints, the Board is unable to fully determine the potential impact. It is not anticipated that any additional FTE will be needed to administer this program. There may be a temporary need for a part-time employee to assist with the initial registration process when the program is first implemented, but once the existing pool of technicians is registered, existing staff should be able to handle the increase in workload. The Board already has a staff person who is a former pharmacy technician who will oversee the registration program.

Agencies of the Commonwealth that offer pharmacy services may take advantage of the opportunity to increase the ratio of technicians working for each pharmacist.

3) Other pertinent matters of interest to the regulated community, government officials, and the public:

The Board is making every effort to assure that the criteria for registration meets the intent of the legislation for improving competency and accountability of personnel involved in accurately dispensing prescriptions without creating undue hardships on the regulated community. The regulated community has been invited to participate in every step of the regulation development process. The Board has solicited input from interested parties throughout the process.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

Proposed regulations were published in the Virginia Register of Regulations on September 9, 2002. Public comment was requested for a 60-day period ending November 8, 2002. The following written comment was received:

John Sisto, representing Medco Health, commented on the requirement that technicians pass a test with recognized standards and administered by a third party. He argues that the only test that currently meets those requirements is the examination of the Pharmacy Technician Certification Board, which is a “relatively difficult examination.” He requests a more practical method of testing the skills of technicians.

Board Response: The Board is in the process of developing an examination which will meet this criteria and only test the core competencies necessary for pharmacy technicians to perform the tasks set forth in the statute. It is planned that this examination will be administered to a large number of candidates the

first year, and thereafter administered at least monthly at a minimum of three sites. There is also a provision for the board to approve other equivalent examinations, provided the examination meets the requirements of regulations. In addition, each pharmacy will be required to provide site-specific training for registered technicians.

An interested citizen in Northern Virginia suggested that: 1) pharmacy technicians be required to provide current results of a certified drug test prior to application, examination or renewal and that such a test be the first step in any inquiry or investigation in which a technician is involved; 2) the pronouns “his” and “he” be replaced with “their” and “they”; and 3) the requirement for a person to be retested who has allowed his registration to lapse for five or more years be changed to require retesting after a lapse of nine months or two years.

Board Response: 1) The statute does not provide for drug testing prior to or as a part of applying for registration as a pharmacy technician. Drug testing may be a requirement for employment, but it is not required for any applicants for a health profession license.

2) The terms "he" and "his" are grammatically and legally correct and refer to either gender of applicant.

3) The Board considered the comment and determined that it was appropriate to require retraining and testing after five years rather than after a shorter period of time. Such a requirement is necessary if someone has been out of the pharmacy for a period of time and needs to completely refresh and update his knowledge and skills. Reinstatement of a lapsed license within the five-year period will necessitate evidence of continuing education.

A Public Hearing before the Board was held on September 30, 2002, at which time there was comment from one person on the proposed rules for registration of pharmacy technicians.

Tom Stallings, representing the Virginia Association of Chain Drug Stores, supported the proposed regulations, which represent a significant amount of work and a “good-faith effort to balance and accommodate all the various and sometimes disparate views that were expressed”. Therefore, his organization urges adoption of regulations in the current form without further modification.

Board Response: The Board appreciates Mr. Stallings comment and has not made further modification to the proposed regulations.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

18 VAC 110-20-20. Fees.

The following fees are established for pharmacy technicians: \$25 for initial application or annual renewal of registration; \$10 for a late fee paid within 60 days of expiration of registration; \$25 for a delinquent fee to reinstate registration; \$125 for reinstatement after revocation or suspension; and \$150 for approval of a training program.

18 VAC 110-20-101. Application for registration as a pharmacy technician.

This section sets forth the requirement for submission of an application fee and an application along with evidence of satisfactory completion of a training program and passage of a board-approved examination. In lieu of the training program and examination, an applicant may present evidence of certification by the Pharmacy Technician Certification Board (PTCB).

18 VAC 110-20-102. Criteria for approval of training programs.

To become an approved program, an entity is required to submit an application on a form approved by the board and a fee. The curriculum must provide instruction in applicable laws and regulations and prepare an applicant to perform the technician tasks specified. Instructors in an approved program must be a licensed pharmacist, a registered technician with at least one year of experience or a PTCB-certified technician. The length of the program must be sufficient to prepare an applicant to sit for the examination and to demonstrate entry-level competence. Program records must be retained for at least two years from date of an applicant's completion or the termination of the program at a site from which they are readily retrievable.

18 VAC 110-20-103. Examination.

Proposed regulations authorize the board to approve one or more examinations to test entry-level competence. An approved examination must be administered by an independent third-party and must meet recognized standards of the Joint Technical Standards for Education and Psychological Testing. The Board may contract with a testing agency for test development and administration. The passing score of the examination must be determined by the Board.

18 VAC 110-20-104. Address of record.

In this section, the technician is required to inform the Board of a change of address within 30 days. Notices required by law or regulation mailed to the address of record are deemed to be legally given.

18 VAC 110-20-105. Renewal and reinstatement of registration.

Pharmacy technicians must renew annually on or before December 31st; registration may be renewed by meeting the renewal requirements and paying the late fee for 60 days after the expiration date. After the 60 days, registration may be reinstated by the executive director provided all requirements have been met and fees have been paid. After 5 years, the registration may not be reinstated, and requirements for initial registration in section 101 must be met.

18 VAC 110-20-106. Requirements for continued competency.

To annually renew a registration, a pharmacy technician must have 5 contact hours of approved continuing education that meet the criteria in current regulations. Provisions are made for extensions or exemptions from the requirement. Regulations also require maintenance of documentation

18 VAC 110-20-111. Pharmacy technicians.

- Each pharmacy that employs or uses technicians must have a site-specific training program for training technicians who work in that pharmacy. The program must include training in specific computer programs, proper use of other equipment being utilized, and pharmacy calculations specific to the practice.
- Documentation of successful completion of the site-specific training program must be maintained during the duration of a technician's employment and for two years following termination at a location that is either on-site or readily retrievable.
- Persons who are engaged in a training program may be allowed to perform acts restricted to pharmacy technicians for no more than nine months without that person becoming registered. The pharmacy is required to maintain on-site and available for inspectors evidence of the persons enrollment in an approved training program.

18 VAC 110-20-270. Dispensing of prescriptions; certification of completed prescription; supervision of pharmacy technicians.

Section 270 is amended to eliminate the acts restricted to a pharmacist, as they are now set forth in § 54.1-3320 (A) of the Code. In addition to those restricted acts, regulations stipulate that the compounding of extemporaneous preparations must be performed under the personal supervision of a pharmacist. In accordance with the Code, the pharmacist is not allowed to monitor at any one time more than four persons performing tasks restricted to a technician (which would include both technicians and trainees).

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The regulatory action will not strengthen or erode the authority and rights of parents, encourage or discourage economic self-sufficiency, or strengthen or erode the marital commitment. The impact on disposable family income is minimal. While there will be a modest fee for registration of technicians, it is possible that technicians who have met the standards set for such registration will be in demand and able to command a slightly higher salary in a pharmacy.